



CERTIFICATE OF ANALYSIS

Name **CARDALIS M** Batch N° **6B3**
Presentation **30 tablets**
Code list **C63520B** Manufacturing date **30-AUG-2012**
Expiry date **30-AUG-2014**

Tests	Specifications	Results
CHARACTERS		
Appearance :	Oblong brown scored tablet	COMPLIES
Average mass :	286.9 - 317.1 mg	303.0
Sizes :		
- Length	13.0 - 14.0 mm	13.6
- Width	5.2 - 6.2 mm	5.8
IDENTIFICATIONS		
Spironolactone: (HPLC/UV diode array)	Rt of test substance concordant with the Rt of reference substance and UV spectra superimposable	COMPLIES
Benazepril: (HPLC/UV diode array)	Rt of test substance concordant with the Rt of reference substance and UV spectra superimposable	COMPLIES
TESTS		
Uniformity of dosage units :	Complies to Ph.Eur. 2.9.40	COMPLIES
Subdivision of tablets :	Complies to Ph. Eur. 0478	COMPLIES
Water content (KF):	<=3.0 %	2.0
Dissolution test :	Complies to Ph.Eur. 2.9.3.1 (With Q>=75%)	
-Mean of Spironolactone dissolved in 45 min	>=75 %	95

This batch has been tested in reference to the dossier in force and has been found to meet the specification requirements

~~COMPLIES / NOT COMPLIES~~

Checked by : Cath. GOOSSAERT

Batch Release number 325284

Batch Release date 13-MAR-2013

ACCEPTED by

Olivier DENIAU
Qualified Person

The undersigned certifies this is a true copy of the results of tests and assays.

